

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte GEOFFREY H. WHITE and WEIYUN YU

Appeal 2007-0850
Application 10/733,292
Technology Center 3700

Decided: May 18, 2007

Before DEMETRA J. MILLS, ERIC GRIMES, and LORA M. GREEN,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a prosthesis for placement in intersecting blood vessels. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse the rejections based on the Cragg patent, vacate the rejections based on the Piplani patent, and enter new grounds of rejection.

BACKGROUND

“It is known to use stents and intraluminal grafts of various designs for the treatment of aneurysms such as aortal aneurysms and for the treatment of occlusive diseases such as the occlusion of blood vessels” (Specification 1). For example, an intraluminal graft can be inserted into the aorta using a catheter, and “[u]pon the release of the graft from the catheter it expands to the size of the aorta above and below the aneurysms and bridges the aneurysms” (*id.*).

The Specification discloses an intraluminal graft having a tubular graft body supported by spaced apart malleable wires having “a generally closed sinusoidal or zig-zag shape, one of the wires being located adjacent to one end of the graft body such that alternate crests or apices of the wire project[] beyond at least part of that end” (*id.* at 2; *see also* Figures 2 and 3). The graft is placed in the desired location in the vessel, and a balloon within the graft is inflated “to cause the alternate crests or apices of the one wire to be urged into contact with the wall of the vessel” (*id.* at 2).

The Specification discloses that “[t]he wire crests may extend across the lumen of a vessel opening into the vessel in which the graft is being placed without occluding that lumen. This allows the intraluminal graft to be used in situations in which the aneurysm to be bridged commences closely adjacent [to] divergent blood vessels” (*id.* at 3).

DISCUSSION

1. CLAIMS

Claims 12-36 are pending and on appeal. Claims 12 and 20 are representative and read as follows:

12. A prosthesis for placement in a lumen of the first vessel that intersects with a second vessel, the prosthesis comprising:

a first end,
a second end, and

wherein at least one of the first and second ends is provided with a wire structure which has a plurality of apices extending beyond at least a portion of the corresponding end such that the plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel.

20. A prosthesis for placement in a lumen of the first vessel that intersects with a second vessel, the prosthesis comprising:

a first end adapted for placement adjacent to a junction between the first vessel and the second vessel, and

a second end,

wherein the first end is reinforced with a wire member which has a plurality of apices extending beyond at least a portion of the first end and across the junction between the first vessel and the second vessel such that the prosthesis does not occlude a lumen of the second vessel.

Thus, claims 12 and 20 are directed to prostheses capable of being placed in a first vessel that intersects with a second vessel. At least one end of the device has a wire structure that includes a plurality of apices extending from the end of the device such that the apices extend across the lumen of the second vessel without occluding it.

By reciting that the wire apices extend across the intersecting vessel's lumen, claims 12 and 20 recite the manner in which the device is to be used. It is well established that "[a]n intended use or purpose usually will not limit the scope of the claim because such statements usually do no more than

define a context in which the invention operates.” *Boehringer Ingelheim Vetmedica v. Schering-Plough Corp.*, 320 F.3d 1339, 1345, 65 USPQ2d 1961, 1965 (Fed. Cir. 2003). Thus, an apparatus capable of performing an intended use will anticipate an apparatus claim, even if the prior art does not disclose that the apparatus was actually put to the intended use recited in the claim. *See In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997).

We therefore interpret claims 12 and 20 to encompass any device having wire apices of sufficient length such that the apices are *capable* of extending across the lumen of a connecting vessel (and meeting the other claim limitations).

Claims 12 and 20 also limit the extending apical wire structure to one that does not occlude the lumen of the second vessel. During prosecution, the Examiner rejected the claims as indefinite because it was unclear whether “occlude” requires total occlusion or encompasses partial occlusion. Appellants argued that “[o]cclude means to shut or close. . . . Partially occlude means partially shut or partially block. Whether the structures defined by claim 20 partially shut or partially block the lumen of the second vessel is irrelevant because that is not what the applicant claims.” (Amendment received July 6, 2005, at 10).

Positions taken during prosecution can limit the scope of the claims. *See Renishaw plc v. Marposs Societa per Azioni*, 158 F.3d 1243, 1249 n.3, 48 USPQ2d 1117, 1121 n.3 (Fed. Cir. 1998) (“Likewise, any interpretation that is provided or disavowed in the prosecution history also shapes the

claim scope.”). Here, Appellants have clearly stated that the claims require only that the apices do not *totally* occlude the lumen of the second vessel.

Thus, overall, we interpret claims 12 and 20 as encompassing an intraluminal graft device having the claimed apical wire structure, in which the wire apices are capable of extending across the lumen of a connecting vessel without completely shutting or closing the connecting vessel.

2. REJECTIONS OVER CRAGG

The Examiner relies on the following references:

Kornberg	US 4,617,932	Oct. 21, 1986
Lazarus	US 5,275,622	Jan. 4, 1994
Piplani	US 5,489,295	Feb. 6, 1996
Cragg	US 5,665,115	Sep. 9, 1997

3. REJECTIONS OVER CRAGG

Claims 21-36 stand rejected under 35 U.S.C. § 102(e) as being anticipated by, or in the alternative under 35 U.S.C. § 103(a) as obvious over, Cragg (Answer 5-6).¹

Claims 21-36 all ultimately depend from either claim 12 or claim 20. Claims 21-36 therefore all require the device’s wire structure to have apices capable of extending across the lumen of a second vessel without occluding it.

The Examiner contends that Cragg meets that limitation because Cragg discloses a prosthesis “provided with a wire structure 11 which has a plurality of apices extending beyond at least a portion of the corresponding

¹ Examiner’s Answer mailed September 21, 2006.

end (in the embodiment in which the graft 13 is shorter than the wire helix as described in col. 3, lines 29-31)” (Answer 5). Based on this disclosure, the Examiner concludes (*id.* at 5-6):

The apices are inherently capable of being located across a lumen of a second vessel since the prosthesis can be deployed in the first blood vessel to a position adjacent the intersection point of a second blood vessel such that the apices are located across a lumen of the second vessel. Alternatively, it would have been obvious that the apices are capable of being located across a lumen of a second vessel for this reason.

Appellants argue that the Examiner has not established that Cragg inherently discloses the device recited in claims 21-36 (Br. 18).

When a reference is silent regarding a particular element, an examiner may refer to extrinsic evidence to demonstrate that the asserted element is inherently present in the reference’s disclosure. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (“[The] gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.”)

However, as stated in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting *Hansgirk v. Kemmer*, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)) (emphasis in original): “Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.”

We agree with Appellants that the Examiner has not established that Cragg meets the limitation requiring the wire apices to be capable of

extending across the lumen of an intersecting vessel. The Examiner relies on Cragg's statement that "[t]he graft 13 may be co-extensive with the wire helix; or it may be shorter than the wire helix" (Cragg, col. 3, ll. 29-31). The Examiner does not point to any other description of this embodiment in Cragg. The Examiner therefore appears to conclude that any apical wire structure extending from the end of an intraluminal prosthesis will inherently be capable of extending across an intersecting vessel.

We do not agree. As noted above, to establish inherency, the Examiner must demonstrate that the asserted inherent element is necessarily part of the reference's disclosure. *Continental Can*, 948 F.2d at 1268, 20 USPQ2d at 1749. However, Cragg does not state that the wire structures extending from the end of the device form apices; the drawings do not appear to show any extending wires that form a shape that would be considered an "apex." In addition, Cragg does not state how far the wire structure may extend from the end of the device. Nor do the drawings provide any clear guidance regarding the proportions of the embodiment described at column 3, lines 29-31. Cragg therefore does not provide sufficient evidence to conclude that the embodiment relied on by the Examiner will necessarily have wire apices capable of extending across the lumen of an intersecting vessel.

Because the Examiner does not point to, and we do not see, sufficient evidence to establish that Cragg's device will necessarily have wire apices capable of extending across the lumen of an intersecting vessel, we do not agree that Cragg inherently meets that limitation. We therefore reverse the anticipation rejection based on Cragg.

The Examiner relies on the same inherency theory to establish obviousness (Answer 5-6). This rejection fails for the same reason as the anticipation rejection. Because the Examiner has not established that Cragg discloses or suggests a prosthesis having an apical wire structure capable of extending across the lumen of an intersecting vessel, we also reverse the obviousness rejection based on Cragg.

4. APPEALED REJECTIONS OVER PIPLANI

Claims 12-16, 19, 20, and 25-36 stand rejected under 35 U.S.C. § 102(e) as being anticipated by, or in the alternative under 35 U.S.C. § 103(a) as obvious over, Piplani (Answer 3-4).

The Examiner cites Figure 4 of Piplani as disclosing a prosthesis having a plurality of wire apices at the ends (*id.* at 3). The Examiner reasons that “[t]he apices are inherently capable of being located across a lumen of a second vessel” (*id.*): “if the prosthesis 20 is inserted into a patient who has arteries . . . which are closer to the aortic bifurcation 221 than the example shown in figure 19, then the apices 132 on wire structure 126 would be located across the lumen of each of the laterally extending arteries” (*id.* at 3-4).

The Examiner also points out that the claims “are drawn to a prosthesis for placement in a vessel in a certain location[,] . . . not . . . to a method of placing the prosthesis in a vessel in a certain location” (Answer 6). The Examiner urges that Piplani’s wire structure is “constructed in a manner similar to that . . . described in U.S. Patent 5,275,622” (Answer 7), which in turn discloses that the wire structure “extends beyond the end of the graft by a relative[ly] large distance of 1 cm” (*id.* at 8). Based on this, the

Examiner concludes that “the Piplani et al. wire structure 126 inherently extends sufficiently far beyond the end of the graft to extend completely across a lumen of the second vessel, as claimed, since it extends farther beyond the end of the graft than appellant's invention” (*id.*).

As discussed *supra*, inherency may not be based on probability or possibility. *In re Oelrich*, 666 F.2d at 581, 212 USPQ at 326. In our view, the Examiner's reasoning does not adequately support a case of inherency. For example, the fact that Piplani's wire structure is made “in a manner similar” to Lazarus' wire structure (Answer 7, *see also* Piplani, col. 5, ll. 34-40), does not mean that Piplani's structure will necessarily have the same dimensions as Lazarus' structure.

However, our review of Piplani leads us to conclude that the reference anticipates many of the appealed claims, but for reasons different than those advanced by the Examiner. We therefore vacate the Examiner's rejections based on Piplani and enter the new rejections set out below.

5. ANTICIPATION BY PIPLANI

Under the provisions of 37 CFR § 41.50(b), we enter the following new ground of rejection: claims 12-16, 19, 20, 22, and 24-36 are rejected under 35 U.S.C. § 102(e) as anticipated by Piplani.

Piplani describes a tubular bifurcated intraluminal graft prosthesis, having first and second ends (Piplani, Figure 4). The device can be placed in the lumen of a first vessel that intersects a second vessel (*see id.* at Figures 13 through 19). The device's main body can be from five to thirty centimeters long, with a diameter of from twelve to thirty millimeters (*id.* at col. 5, ll. 16-22).

Piplani's device comprises an expandable spring attachment means 126, having a generally sinusoidal or zig-zag shape, with a plurality of wire apices 132 that extend from the body of the graft (*id.* at Figure 4; col. 5, ll. 29-58.) The spring attachment must be physically expanded "from an initial compressed or collapsed position to a subsequent expanded position" to allow it to press against the inner surface of a vessel (*id.* at col. 5, ll. 39-40). Piplani's device also has first and second wires not at the end of the prosthesis (*id.* at col. 5, ll. 23-27).

Regarding the limitation in claims 12 and 20 requiring the device's wire apices to be capable of extending across an intersecting vessel, Piplani discloses that

the apices 132 lie in three longitudinally spaced-apart parallel planes extending transversely of the axis of the expandable spring attachment means in which the first plane is disposed internally of the open end and the second plane lies in a position which is external of but in close proximity to the open end *and the third plane is spaced a substantial distance beyond the open end.*

(*Id.* at col. 5, ll. 51-58, emphasis added.)

Thus, Piplani's graft has two sets of wire apices that extend beyond the body of the graft. One set of apices is "in close proximity" to the open end of the graft, while the other set of apices is "a substantial distance" from the end of the graft (*id.* at col. 5, ll. 55-58).

In view of the drawings, the explicitly stated dimensions, and the disclosure that one set of wire apices extends "a substantial distance" from the body of the graft, it is reasonable to conclude that the wire apices of Piplani's device would extend a sufficient distance from the body of the

graft such that the apices would be capable of extending across the lumen of an intersecting vessel, including a renal artery. Therefore, Piplani's device reasonably appears to meet the structural limitations of claims 12-16, 19, 20, 22, and 24-36.

As stated in *In re Best*, 562 F.2d 1252, 1254-55, 195 USPQ 430, 433 (CCPA 1977):

[W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

In reviewing Appellants' arguments, we do not find any evidence demonstrating that this conclusion is not reasonable. On the current record, Appellants have not met their burden under *In re Best* of establishing a difference between the claims and prior art.

Appellants urge that Piplani teaches away from deploying the graft in the manner recited in claim 12 and 20 (Br. 9). However, as discussed *supra*, a prior art device capable of performing the intended use will anticipate an apparatus claim, even if the device is not actually used in the manner recited in the claim. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Moreover, "the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis." *Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998) (citation omitted).

Appellants argue that placing Piplani's device in a vessel with the apices across an intersecting vessel lumen would yield a non-functional result because the lumen would not exert enough tension on the wire structure to allow the hooks opposite the lumen to penetrate the vessel wall (Br. 10). We do not find this argument persuasive.

Piplani discloses that the apices of the device extend "a substantial distance" from the body of the graft, and therefore Piplani's device reasonably appears to comprise apices capable of extending across the lumen of an intersecting vessel without completely occluding it. The device disclosed by Piplani therefore meets the structural limitations of the instant claims. It makes no difference, with respect to anticipation, whether the hooks on Piplani's device would function as intended if it were deployed as proposed by Appellant.

Appellants further argue that Piplani does not describe the apices being in a generally zig-zag or sinusoidal configuration (Br. 11-12; Reply Br. 5-6). We do not agree. The claims require only a "generally" sinusoidal or zig-zag structure. The term "generally" encompasses some variation, including the structure of the expandable spring attachment depicted in Figure 4.

Appellants further argue that Piplani does not disclose first and second wires not at the end of the prosthesis (Br. 12). We do not agree. Piplani states that "[r]adiopaque markers 121 are provided on the main body 112 . . . and can be formed of a suitable material *such as lengths of platinum wire* secured to the fabric of the graft by suitable means . . ." (Piplani, col. 5, ll. 23-27, emphasis added).

To summarize, one of ordinary skill viewing Piplani would have reasonably concluded that the disclosed device meets all the limitations in claims 12-16, 19, 20, 22, and 24-36.

6. OBVIOUSNESS OVER PIPLANI

Under the provisions of 37 C.F.R. § 41.50(b), we enter the following new ground of rejection: claims 17, 18, 21, and 23 are rejected under 35 U.S.C. § 103(a) as being obvious over Piplani and Kornberg.

As discussed *supra*, Piplani describes a prosthetic device meeting all of the limitations of claims 12-16, 19, 20, 22, and 24-36. Piplani does not disclose that the apical wire structure is formed of stainless steel, as recited in claim 17, or of biocompatible plastic, as recited in claim 18. Nor does Piplani disclose that the apices are formed of a malleable material, as recited in claims 21 and 23.

However, as pointed out by the Examiner (Answer 5), Kornberg teaches that “flexible resilient plastic” and “surgical steel” were known to be suitable as support materials for aortic grafts (Kornberg, col. 4, ll. 8-17 and 25-29). Because malleable plastic and surgical steel were known to be useful as support materials for aortic grafts, one of ordinary skill would have considered it obvious to use those materials to construct the expandable spring attachment that supports Piplani’s graft device.

Appellants argue that the combination of Piplani and Kornberg does not render claims 17 and 18 obvious because Kornberg does not remedy Piplani’s failure to anticipate independent claim 12 (Br. 16-17). We do not find this argument persuasive. As discussed *supra*, in our view, one of

ordinary skill would have reasonably concluded that Piplani discloses all of the limitations in claim 12.

To summarize, we agree with the Examiner that Piplani anticipates claims 12-16, 19, 20, 22, and 24-36, and renders claims 17, 18, 21, and 23 obvious when viewed with Kornberg. However, because we base these conclusions on a rationale different from that applied by the Examiner, we designate these as new grounds of rejection. 37 C.F.R. § 41.50(b).

SUMMARY

We reverse the anticipation and obviousness rejections over Cragg. We vacate the Examiner's rejections using the Piplani reference, and enter new anticipation and obviousness rejections based on that reference.

Time Period for Response

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.

37 C.F.R. § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner

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(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record

REVERSED, 37 C.F.R. § 41.50(b)

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